K033949

JUL - 2 2004

TAB D

510(k) SUMMARY
Varilux® VisionPrint™ System
Essilor International, Inc.

This 510(k) summary of safety and effectiveness for the Varilux® VisionPrint™ System is submitted in accordance with the requirements of SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Essilor International, Inc.
Address:	c/o Essilor of America, Inc. 2400 118th Avenue North St Petersburg, FL 33176 (727) 572-0844 (727) 592-0358 (FAX) gwalsh@essilorusa.com
Contact Person:	Marc J. Scheineson, Esq. Regulatory Counsel
Telephone:	(202) 414-9243 (telephone) (202) 414-9299 (fax)
Preparation Date:	December 19, 2003
Device Trade Name:	Varilux® VisionPrint™ System or VPS
Common Name:	Eye Movement Monitor
Classification Name:	Eye Movement Monitor (see 21 C.F.R. § 886.1510)
Product Code:	HLL
Predicate Device:	OBER2 Eye Movement Monitor, 510(k) # K902954
Device Description:	The VPS is a non-invasive ultrasonic device intended to measure the pattern of eye and head movement when viewing lateral LED fixation lamps. It consists of a headset and a main body with an ultrasonic transmitter. Two ultrasonic receivers are imbedded in the center nosepiece of the headset. The patient wears the headset and looks at three orange LED fixation lamps in the main body as they light up in succession. As the patient follows the lights from

	side to side, the device measures the degree of head movement from the center light against a target angle of 40° and a standard deviation. Eye movement is extrapolated to fill the remaining vision angle. The calculated ratio of head/eye movement is used to determine the shape of the peripheral and central fields of the progressive spectacle lenses.
Specifications:	The VPS emits ultrasound at sound pressure levels of 115 dB at 40 kHz, to which the patient is exposed for approximately 2 minutes during testing.
Intended Use:	The VPS is a non-invasive ultrasonic device intended to measure the pattern of eye and head movement when viewing lateral visual stimulus, to use as a guide for prescribing progressive power eyeglass lenses.
Performance Data:	In a clinical study, 175 presbyopic patients were measured for head and eye movement by two devices: an electromagnetic sensor -- the Polhemus Fastrak -- and an ultrasound transmitter and receivers. The measurement by the ultrasound device was reproducible. Subjects were measured on two separate days. For 90% of those subjects, the differences between the measurements were lower than 0.20. Moreover, the standard deviation – *i.e.*, the dispersion among the 20 measurements for each subject taken in one session – was similarly reliable, with 98% of the measurement differences lower than 0.11. The measurements taken by the ultrasound device showed a close correlation with those taken by the electromagnetic Polhemus Fastrak.
CONCLUSIONS:	Based on the foregoing and other information contained in this application, Essilor believes that the Varilux® VPS is substantially equivalent to its claimed predicates under conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Essilor International, Inc.
c/o Marc J. Scheineson, Esq.
Alston & Bird, L.L.P.
601 Pennsylvania Avenue, N.W.
Washington, DC 20004-2601

Re: K033949
Trade/Device Name: Varilux^{R} VisionPrint^{TM} System
Regulation Number: 21 CFR 886.1510
Regulation Name: Eye Movement Monitor
Regulatory Class: Class II
Product Code: HLL
Dated: June 25, 2004
Received: June 25, 2004

Dear Mr. Scheineson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033949

Device Name: Varilux® VisionPrint™ System (VPS)

Indications For Use:

The VPS is a non-invasive ultrasonic device intended to measure the pattern of eye and head movement when viewing lateral visual stimulus, to use as a guide for prescribing progressive power eyeglass lenses.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033949